

**DISTRICT OF COLUMBIA
OFFICE OF ADMINISTRATIVE HEARINGS**

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DISTRICT OF COLUMBIA
DEPARTMENT OF HEALTH

Petitioner,

v.

CVS PHARMACY #1839
Respondent.

Case No.: DH-I-08-D100282

FINAL ORDER

I. INTRODUCTION

This case arises under the Civil Infractions Act of 1985, as amended (D.C. Code, 2001 Ed. §§ 2-1801.01 *et seq.*) and D.C. Code, 2001 Ed. §§ 47-2885.10(a)(3)¹ and 47-2885.13(a);²

¹ D.C. Code, 2001 Ed. § 47-2885.10(a)(3) reads in pertinent part:

The Mayor may refuse the issuance or renewal, or may revoke, or may suspend for not more than 90 days, a license issued pursuant to this part for:

(3) Selling, or offering for sale, adulterated or misbranded drugs or devices.

² D.C. Code, 2001 Ed. § 47-2885.13(a) reads in full:

Drugs which may deteriorate shall at all times be stored under conditions specified on the label of the original container and in accordance with applicable District of Columbia or federal laws or regulations, and shall not be sold or dispensed after the expiration date designated on the label of the original container, and in accordance with applicable District of Columbia or federal laws or regulations.

22 District of Columbia Municipal Regulations (“DCMR”) 1901.6 (this provision was listed in the NOI as 22 DCMR 1909.6; however, the regulations were recodified in January 2008 and 1901.6 is the current citation);³ 22 DCMR 1911.11 (this provision was listed in the NOI as 22 DCMR 1912.11; however, given the recodification in January 2008 and 1911.11 is the current citation);⁴ and 22 DCMR 1503.1.⁵ By Notice of Infraction D100282, served on January 2, 2008, the Government charged Respondent, CVS Pharmacy #1839, with violating these provisions of the governing regulatory scheme by mislabeling medicines that were prepared by the pharmacist for individual sale but then returned to stock (a “Return to Stock” violation), selling or offering for sale expired prescription drugs and over-the-counter (“OTC”) drugs, storing expired prescription medications with unexpired drugs, and failing to properly fill out federal Drug Enforcement Agency (“DEA”) forms associated with certain prescription medications, as required by 21 Code of Federal Regulations (“CFR”) 1306(5)(a). The Government alleged that the violations occurred on October 17, 2007, at 1990 K St., NW and sought \$5,000 in fines. Respondent filed a plea of Deny on January 15, 2008, but on June 2, 2008, amended its plea by

³ 22 DCMR 1901.6 reads in full:

Drugs and medical devices with expired dating, or that are otherwise misbranded or adulterated, shall not be stored with currently dated products or those that are safe for their intended purposes, but shall be separated from active stock and so identified.

⁴ 22 DCMR 1911.11 reads in full:

All drugs and medical devices held by a pharmacy shall be stored in a proper and safe manner as to insure complete and accurate identification of the product, in an appropriate container or package that provides for protection of the product, and as required by this chapter and other applicable federal and District of Columbia laws or regulations or that of the manufacturer.

⁵ 22 DCMR 1503.1 reads in full:

Accountability audits in pharmacies shall be accomplished through a review of invoices, prescription file, other records required by federal and District of Columbia laws and regulations, and this chapter.

waiving its right to a hearing and moving for a reduction in the proposed fine.

On June 13, 2008, I consolidated this matter with nine other Notices of Infraction (“NOI”). OAH Rule 2919. However, I also separated non-“Return to Stock” violations for resolution in separate Final Orders. OAH Rule 2919.3. During a hearing on a different NOI issued to CVS, I granted the parties’ request to stay this matter so they could attempt to settle this and nine other outstanding NOIs. They were unsuccessful and both parties have consented to this matter being resolved on the entire record, including documents that were filed with the NOI and Respondent’s pleas. Based on these documents and the entire record in this case, I make the following findings of fact and conclusions of law.

II. FINDINGS OF FACT

1. On October 17, 2007, Government Inspector Janis Jackson, Pharmacist, inspected store number 1839, located at 1990 K St., NW. During the investigation, Inspector Jackson discovered that Respondent had: a) three expired prescription drugs stored with current-dated medications and these expired drugs were for sale; b) five different expired OTC drugs for sale; and c) improperly filled out federal Drug Enforcement Agency (“DEA”) forms associated with certain prescription medications.

2. Respondent offered for sale three expired prescription drugs and five different expired OTC medications. Respondent stored in its active stock expired prescription drugs with unexpired medication. Respondent failed to properly fill out federal Drug Enforcement Agency (“DEA”) forms associated with certain prescription medications.

III. DISCUSSION AND CONCLUSIONS OF LAW

The Government alleged that Respondent violated D.C. Code, 2001 Ed. §§ 47-2885.10(a)(3) and 47-2885.13(a), 22 DCMR 1901.6, 1911.11, and 1503.1. by selling or offering for sale expired prescription and OTC drugs, storing expired prescription drugs with unexpired medications, and failing to properly fill out federal Drug Enforcement Agency (“DEA”) forms associated with certain prescription medications, as required by 21 CFR 1306(5)(a). Respondent admits that it sold the expired OTC drugs and failed to fill out properly federal Drug Enforcement Agency (“DEA”) forms associated with certain prescription medications. However, Respondent maintains that the expired prescription drugs stored in the pharmacy were compounding agents that do “not have an expiration date[s] in the same manner as prescription drugs.” *See* Respondent’s June 2, 2008, Reply. Therefore, Respondent denies that it had expired prescription drugs in its pharmacy on the date of the inspection.

First Violation

In this violation, the Government alleged that Respondent sold or dispensed drugs after the expiration date and stored these expired drugs with unexpired medication (there is also a Return to Stock charge in this violation; however, as noted above the Return to Stock violation was resolved in a Final Order issued June 16, 2008). D.C. Code, 2001 Ed. §47-2885.10(a)(3) specifically prohibits the sale “or offering for sale, adulterated or misbranded drugs or devices.”⁶

⁶ D.C. Code, 2001 Ed. §47-2885.10(a)(3) governs the licensing of pharmacies and pharmacists and, on its face, does not appear to provide a means for the imposition of a civil infraction. However, D.C. Code, 2001 Ed. § 47-2885.20(d) provides that:

Civil fines, penalties, and fees may be imposed as alternative sanctions for any infraction of the provisions of this part, or any rules or regulations issued under the authority of this part, pursuant to Chapter 18 of Title 2. Adjudication of any infraction of this chapter shall be pursuant to Chapter 18 of Title 2.

Hence, enforcement of a violation of D.C. Code, 2001 Ed. §§ 47-2885.10 and 47-2885.13 may occur as either a license enforcement action or civil infraction, as occurred here.

22 DCMR 1909.6, while somewhat confusing, implies that an expired drug is a misbranded or adulterated drug. D.C. Code, 2001 Ed. § 47-2885.02(8) defines the term ““over-the-counter drug” [as] drugs which may be sold without a prescription” A “drug” is defined in the statute as:

- (C) Any chemical substance (other than food) intended to affect the structure or any function of the body of man or other animal; and
- (D) Any substance *intended for use as a component* of any items specified in subparagraph (A), (B), or (C) of this paragraph, but does not include medical devices or their components, parts, or accessories.

D.C. Code, 2001 Ed. § 47-2885.02(3) (emphasis added).

Consequently, the pertinent statutes establish that it is a violation of D.C. Code, 2001 Ed. §47-2885.10(a)(3) to sell expired prescription drugs (including, according to D.C. Code, 2001 Ed. § 47-2885.02(3)(D), components of such substances) and OTC drugs. The Government has proven by a preponderance of evidence that Respondent did sell or offer for sale expired prescription medication and OTC drugs on October 17, 2007. While Respondent argues that the prescription compounding agents do not “have an expiration date in the same manner as prescription medication,” the applicable regulation explicitly covers “component” substances.” Respondent has not explained how it reached the suggested conclusion. Respondent also failed to dispute Inspector Jackson’s report that the compounding agents were in use at its pharmacy on October 17, 2007, and had labels with expiration dates that had passed. In fact, Respondent acknowledged that those compounding agents were in use, so I conclude that these drugs were being offered for sale on October 17, 2007, even though Inspector Jackson did not see the drugs actually being sold. Consequently, Respondent is liable for violating D.C. Code, 2001 Ed. §47-2885.10(a)(3).

A violation of D.C. Code, 2001 Ed. §47-2885.10(a)(3) is a Class 1 infraction punishable by a \$2,000 fine for a first offense. 16 DCMR 3201.1(a); 16 DCMR 3615.1(f). There are no fines associated with violations of 22 DCMR 1901.6 or 22 DCMR 1911.11. The Government sought a \$2,000 fine. Respondent argued that a \$750 fine is appropriate. I conclude there are no mitigating circumstances and impose a \$2,000 fine.

Second Violation

In this violation, the Government alleged that Respondent sold or dispensed drugs after the expiration date and stored these expired drugs with unexpired medication. There is no discernible difference between this violation and the first violation, except that in the first violation the Government claimed that Respondent violated D.C. Code, 2001 Ed. §47-2885.10(a)(3) and in the second violation the Government claimed that Respondent violated D.C. Code, 2001 Ed. §47-2885.13(a). The factual predicate for this alleged violation is exactly the same as that supporting the first violation. As the two charges are identical and rely on identical facts, I conclude the charges are duplicative and I hold Respondent liable for only one violation D.C. Code, 2001 Ed. §47-2885.10(a)(3) (and the associated regulations). The second violation is dismissed. *D.C. Dep't of Consumer and Regulatory Affairs v. Givens*, CR-I-06-Q102780, (OAH 2006).

Third Violation

By way of its plea of Admit with Explanation, Respondent has admitted that on October 17, 2007, it had not properly filled out certain DEA forms associated with prescription drugs, as required by 21 CFR 1306(5)(a), in violation of 22 DCMR 1503.1. Consequently, Respondent is liable for violating 22 DCMR 1503.1.

A violation of 22 DCMR 1503.1 is a Class 1 infraction punishable by a maximum \$2,000 fine for a first offense. 16 DCMR 3201.1(a); 16 DCMR 3616.1(h). The Government sought a \$2,000 fine for this violation. Respondent countered that a \$1,000 fine was appropriate. I conclude there are no mitigating circumstances and impose a \$2,000 fine.

IV. ORDER

Therefore, based on the entire record herein, it is this 1st day of July 2008

ORDERED that Respondent CVS Store #1839 is **LIABLE** for violating D.C. Code, 2001 Ed. §47-2885.10(a)(3), 22 DCMR 1901.6, 1911.11, and 1503.1 as charged in Notice of Infraction No. D100282; it is further

ORDERED that Respondent shall pay a fine in the amount of **FOUR THOUSAND DOLLARS (\$4,000)** in accordance with the attached instructions within twenty (20) calendar days of the date of mailing of this Order (15 calendar days plus 5 days for service by mail pursuant, to D.C. Code, 2001 Ed. §§ 2-1802.04 and 2-1802.05); it is further

ORDERED that, if Respondent fails to pay the above amount in full within 20 calendar days of the date of mailing of this Order, by law, interest shall accrue on the unpaid amount at

the rate of 1½ % per month or portion thereof, beginning with the date of this Order, pursuant to D.C. Code, 2001 Ed. § 2-1802.03(i)(1); it is further

ORDERED that failure to comply with the attached payment instructions and to remit a payment within the time specified will authorize the imposition of additional sanctions, including the suspension of Respondent's licenses or permits, pursuant to D.C. Code, 2001 Ed. § 2-1802.03(f), the placement of a lien on real or personal property owned by Respondent, pursuant to D.C. Code, 2001 Ed. § 2-1802.03(i), and the sealing of Respondent's business premises or work sites, pursuant to D.C. Code, 2001 Ed. § 2-1801.03(b)(7); it is further

ORDERED that the appeal rights of any person aggrieved by this Order are stated below.

July 1, 2008

/SS/
Jesse P. Goode
Administrative Law Judge